67. (New) The method according to claim 66 comprising at least 3 administrations per year.

REMARKS

Claims 1-58 are pending in the present application. Claims 30-32 and 34-58 have been cancelled without prejudice or disclaimer of the subject matter contained therein. Claims 59-67 have been added and contain subject matter removed from original claims 10-14 and 33. No new matter has been added.

The Examiner has required election in the present application between:

Group I, claims 1 (in part), 2-29 and 33 drawn to a method for in vivo down-regulation of amyloid protein in an animal, wherein presentation of amyloidogenic polypeptide to the immune system is effected by introducing amyloidogenic polypeptide or its analogue into the animal cell, classified in class 435, subclass 7.1;

Group II, claims 1(in part) and 30-32, drawn to a method for in vivo down-regulation of amyloid protein in an animal, wherein presentation of amyloidogenic polypeptide to the immune system is effected by introducing nucleic acids encoding the modified amyloidogenic polypeptide or its analogue into the animal cell, classified in class 435, subclass 6;

Group III, claims 1 (in part) and 47, drawn to a method for in vivo down-regulation of amyloid protein in an animal, wherein presentation of amyloidogenic polypeptide to the immune system is effected by administering a non-pathogenic microorganism or virus which is carrying a nucleic acid fragment which encodes and expresses the amyloidogenic polypeptide or analogue, classified in class 435, class 5;

Group IV, claim 34, drawn to a method for treating and/or preventing Alzheimer's disease or other diseases and conditions characterized by amyloid deposits, classified in class 514, subclasses 2 and 12;

Group V, claims 35-37, drawn to an analogue of an amyloidogenic polypeptide and an immunogenic composition comprising the same, classified in class 530, subclass 350, class 530, subclass 300;

Group VI, claims 38-46 and 48-50, drawn to a nucleic acid fragment, a vector, a host cell and a method for the preparation of the cell, classified in class 530, subclass 23.5, class 435, subclasses 320.1 and 325;

Group VII, claim 51 (in part), drawn to a method for the identification of a method of a modified amyloidogenic polypeptide which is capable of inducing antibodies, wherein the polypeptide is prepared by peptide synthesis and presented to the cell, classified in class 435, subclass 7.1;

Group VIII, claims 51 (in part), 53 and 54, drawn to a method for the identification of a modified amyloidogenic polypeptide which is capable of inducing antibodies, wherein the polypeptide is prepared by genetically engineering techniques and is presented to the cell by introducing nucleic acid sequence(s) encoding a modified amyloidogenic polypeptide, classified in class 435, subclass 6; and

Group IX, claims 52 and 55-57, drawn to a method for the preparation of an immunogenic composition comprising at least one modified amyloidogenic polypeptide, classified in class 514, subclasses 2 and 12.

For the purpose of examination of the present application, Applicants elect, without traverse, Group I, claims 1-29 and 33. Claim 1 has been amended and is now directed protein vaccination.

The Examiner has also required Applicant to make an election of species (see paragraph 9 of the Office Action). Referring to the specific election required under paragraph 9, Applicant's species elections are as follows:

(i) analogue of amyloidogenic polypeptide;

(ii) at least one foreign T helper lymphocyte epitope (T_H epitope) is introduced;

(iii) diphtheria toxoid epitope (see claim 60);

(iv) a substantially specific binding partner for an APC specific surface antigen;

(v) cytokine;

(vi) polyhydroxypolymer;

(vii) beta amyloid;

The species election in subparagraph (viii) of paragraph 9 is no longer relevant given the amendment of claim 1 and the election of the claims of Group I.

Should the Examiner require a further species election for items (ii), (iii), (iv), (v) or (vi) above, Applicants elect the following:

(ii) an artificial MHC-II peptide binding sequence;

(iii) SEQ ID NO: 4;

(iv) a carbohydrate for which there is a receptor on the B-lymphocyte or the APC;

(v) HSP70; and

(vi) palmitoyl.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson (Reg. No. 30,330) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By _____
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Attachment: Version with Markings to Show Changes Made

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope to: Commissioner of Patents and Trademarks, Washington D.C. 20231 on: October 15, 2002
(Date of deposit)

BIRCH, STEWART, KOLASCH & BIRCH, LLP

Tillie Mead
(Signature)

October 15, 2002
(Date of Signature)

VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) A method for *in vivo* down-regulation of amyloid protein in an animal, including a human being, the method comprising effecting presentation to the animal's immune system of an immunogenically effective amount of

[- at least one amyloidogenic polypeptide or subsequence thereof which has been formulated so that immunization of the animal with the amyloidogenic polypeptide or subsequence thereof induces production of antibodies against the amyloidogenic polypeptide, and/or]

- at least one analogue of the amyloidogenic polypeptide wherein is introduced at least one modification in the amino acid sequence of the amyloidogenic polypeptide which has as a result that immunization of the animal with the analogue induces production of antibodies against the amyloidogenic polypeptide.

10. (Amended) The method according to claim 3, wherein the foreign T-cell epitope is promiscuous[, such as a foreign T cell epitope which is selected from a

natural promiscuous T cell epitope and an artificial MHC-II binding peptide sequence].

11. (Amended) The method according to claim 10, wherein the natural T-cell epitope is selected from a Tetanus toxoid epitope [such as P2 or P30], a diphtheria toxoid epitope, an influenza virus hemagluttinin epitope, and a *P. falciparum* CS epitope.

12. (Twice Amended) The method according to claim 3, wherein the first moiety is <u>selected from</u> a substantially specific binding partner for a B-lymphocyte specific surface antigen <u>and a substantially specific binding partner</u> [or]<u>for</u> an APC specific surface antigen [such as a hapten or a carbohydrate for which there is a receptor on the B lymphocyte or the APC].

13. (Twice Amended) The method according to claim 3, wherein the second moiety is selected from a cytokine [such as interferon y (IFN y) or an effective part thereof, Flt3L or an effective part thereof, interleukin 1 (IL-1) or an effective part thereof, interleukin 2 (IL-2) or an effective part

thereof, interleukin 4 (IL-4) or an effective part thereof, interleukin 6 (IL-6) or an effective part thereof, interleukin 12 (IL-12) or an effective part thereof, interleukin 13 (IL-13) or an effective part thereof, interleukin 15 (IL-15) or an effective part thereof, and granulocyte macrophage colony stimulating factor (GM-CSF) or an effective part thereof]; a hormone; and a heat-shock protein [such as HSP70 or an effective part thereof, HSP90 or an effective part thereof, HSC70 or an effective part thereof, GRP94 or an effective part thereof, and calreticulin (CRT) or an effective part thereof].

14. (Twice Amended) The method according to claim 3, wherein the third moiety is of lipid nature[, such as a palmitoyl group, a myristyl group, a farnesyl group, a gernayl geranyl group, a CPI-anchor, and an N-acyl diglyceride group,] or wherein the third moiety is a polyhydroxypolymer [such as a polysaccharide].

15. (Amended) The method according to claim [14]65, wherein the polysaccharide serves as a carrier

backbone to which the amyloidogenic polypeptide and the foreign T cell epitope are separately bound.

33. (Twice Amended) The method according to claim[s] 22, which includes at least one administration[/introduction] per year[, such as at least 2, at least 3, at least 4, at least 6, and at least 12 adminstrations/introductions].